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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,032	09/26/2003	Ludwig J. Weimann	ULT1. LU-08-CIP	7698

3775 7590 10/02/2006

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,032	WEIMANN, LUDWIG J.	
	Examiner	Art Unit	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 10 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-7, 11 and 15-25 is/are rejected.
- 7) ☒ Claim(s) 1, 8-10, 12 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/13/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 5/13/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Objections

Claims 1, 9, and 19 are objected to because of the following informalities: There are minor deficiencies in each claim, claims 1 and 19 have two step (d)'s and no step (c), and claim 9 does references step (d) but it is unclear which step (d) is being referenced and therefore, is vague and indefinite. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 11 and 15-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 6, 7, 8, 15 and 16 of U.S. Patent No. 6,712,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

A method for sonoporation for intradermal delivery of a microparticles suspension containing a beneficial substance to be released into an area of a patient's skin comprising: (a) providing a container having a first end and a second end, said second end having thereon a ring of skin-removable resilient medical adhesive material and being covered by a removable protective film; (b) submerging the tip of an ultrasound horn in said microparticles suspension through said first end of the container; (c) removing the protective film; and (d) placing said second end in contact with an area of a patient's skin intended to receive said beneficial substance and (e) applying ultrasound radiation to said microparticles suspension at a frequency, an intensity, for a period of time, and at a distance from the skin, effective to generate cavitation bubbles, wherein said cavitation bubbles collapse and transfer their energy into the skin area thus causing the formation of pores in the skin area; and wherein said ultrasound radiation intensity and distance from the skin area are also effective in generating ultrasonic jets, said ultrasonic jets driving said

Art Unit: 3763

microparticles through said formed pores into the skin area with a majority of the microparticles remaining intact.

While patent claim 1 requires:

A method for sonoporation for intradermal delivery of a microparticles suspension containing microencapsulated drugs comprising: (1) providing a container having a first end and a second end, said second end being covered with a porous membrane covered by a removable protective film and containing said microparticles suspension; (2) submerging a removably connected tip of an ultrasound horn in said microparticles suspension containing microencapsulated drugs through said first end of the container; (3) placing said porous membrane in contact with said skin area; and (4) applying ultrasound radiation to said microparticles suspension containing microencapsulated drugs wherein said ultrasound radiation is applied at a frequency, an intensity, for a period of time, and at a distance from the skin, effective to generate cavitation bubbles, wherein said cavitation bubbles collapse and transfer their energy into the skin area thus causing the formation of pores in the skin area; and wherein said ultrasound radiation intensity and distance from the skin area are also effective in generating ultrasonic jets, said ultrasonic jets driving said microparticles suspension containing microencapsulated drugs through a porous membrane and said formed pores into the skin area, further comprising removing said protective film before placing said membrane in contact with the skin area.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims 1, 4, 5, 6, 7, 8, 15 and 16 encompass application claims 1-7, 11 and 15-25. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Allowable Subject Matter/Claim Objections

Claims 8, 10, 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/23/2006


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